

## **REMARKS/ARGUMENTS**

### **A. Status of the Claims**

Claims 1-25 were originally filed. Claims 1-25 were subject to a Restriction Requirement. Claim 25 was elected for prosecution on the merits. In a previous response, Applicants added claims 26-29. Claims 25-29 have been rejected. Applicants have amended claims 25 and 28 to add “hay” before fever. Support for this amendment can be found, for example, in paragraph [0005] of the published application. Claims 25-26 have been amended to recite that test method comprises the subcutaneous injection of allergens that had been treated with a composition. Support for the amendment can be found, for example, in paragraphs [0022-0024] and [0145-0146] of the published application. Claim 27 is canceled without prejudice. Claim 28 is amended to recite that the allergen is a solution of *Aspergillus fumigatus* that had been treated with the composition, thereby incorporating claim 29. Consequently, Applicants have deleted all other allergens in claim 28. Claim 28 is amended to change “residue” to “sample”. Support for the amendment can be found, for example, in paragraphs [0140] and [0145-0146] of the published application. Claim 29 is canceled without prejudice. New claim 30 is added. Claim 30 is a method claim that is intended to clarify an embodiment of Applicant’s claimed invention. Solely in response to the Examiner’s request, Applicants have cancelled claims 1-24 which is the non-elected subject matter.

No new matter is added and the amendments are fully supported by the specification.

### **B. 35 U.S.C. § 112, First paragraph (New Matter)**

Claims 25 and 28 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. The Office Action states that the claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time of the application was filed, had possession of the claimed invention. The Office Action states that the amended claims contain new matter because throughout the specification ‘hay fever’, not ‘fever’ is listed as the allergic response. Applicants respectfully traverse.

Without acquiescing to the propriety of the rejection, Applicants have amended claims 25 and 28 to recite “hay fever”.

Therefore, Applicants respectfully request that this rejection be withdrawn.

**C. Under 35 U.S.C. § 112, Second paragraph (Indefiniteness)**

Claims 28 and 29 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. First, the Office Action states that claim 28 contains a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite. Specifically, claim 28 recites the broad recitation mold, and the claim also recites mold spores which is the narrower statement of the range/limitation. Second, the Office Action states that the claims as written are ambiguous because of the phrase “using a residue from treatment of the allergen with the composition.” Applicants respectfully traverse.

For the sole purpose of expediting prosecution, Applicants have clarified in claim 28 that the allergen is a solution of a solution of *Aspergillus fumigatus* that had been treated with a composition selected from a group consisting of a hypohalous acid, a hypohalous acid salt, and a combination thereof. Therefore, this rejection is now moot. Additionally, Applicants have changed the term “residue” to “sample” in claims 28-29 to clarify the claim further.

Therefore, Applicants respectfully request that this rejection be withdrawn.

**D. Under 35 U.S.C. § 103(a)**

*Over Camper in view of Rutala*

Claims 25-29 are rejected under 35 U.S.C. §103(a), as allegedly being unpatentable over Camper *et al.* (U.S. Pat. No. 6,589,568)(“Camper”) in view of Rutala *et al.* (Infect. Control Hosp. Epidemiol., 1998, Vol. 19, pages 323-327)(“Rutala”). Applicants respectfully traverse. Applicants submit that the references are missing at least one element which is present Applicants’ currently pending claims.

In order to establish a *prima facie* case of obviousness, the Examiner must demonstrate that 1) the references teach all the claimed elements; 2) there is a suggestion or motivation in the prior art to modify or combine the reference teachings; and 3) there is a reasonable expectation of success. MPEP § 2143; In re Vaeck 20 USPQ2d 1438 (Fed. Cir. 1991). In *KSR*, the Supreme Court particularly emphasized "the need for caution in granting a patent based on the combination of elements found in the prior art," *Id.* at \_\_\_, 82 USPQ2d at 1395, and discussed circumstances in which a patent might be determined to be obvious. Importantly, the Supreme Court reaffirmed principles based on its precedent that "[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *Id.* at \_\_\_, 82 USPQ2d at 1395. (MPEP2141) For the reasons described below, the cited references fail to establish a *prima facie* case of obviousness and Applicants respectfully traverse.

(1) Camper and Rutala all fail to teach all of the elements

First, Applicants have amended claim 25-26 and 28 to recite that that test method comprises the subcutaneous injection of allergens that had been treated with a composition. In contrast, Camper and Rutala both fail to teach that their method comprises the subcutaneous injection of allergens that had been treated with a composition. Camper specifically does not look at allergens that have already been treated with a composition selected from a group consisting of a hypohalous acid, a hypohalous acid salt, and a combination thereof.

Second, Camper discloses the sodium hypochlorite stimulates the immune system to alleviate allergies. (See abstract of Camper). In contrast, Applicants does not use stimulation of the immune system to alleviate allergies. In fact, Applicants test an already inactivated allergen solution by using a subcutaneous injection of the already inactivated allergen solution in animal and evaluate that response. Rutala clearly does not address this issue as well.

Third, Applicants assert that Camper and Rutala do not disclose that an allergen is selected from the group consisting of pollen, mold, pet dander, dust mite, cockroach and mixtures thereof as recited claim 25. While Camper discloses allergies generally in the specification, Camper fails to disclose which allergens its invention is directed as countless

number of allergens is known in the literature. Furthermore, Camper fails to disclose any examples involving allergies, let alone allergens, in the “Examples section” of the specification. The Examples in Camper relate to severe ailments and diseases such as HIV, hemorrhoids or respiratory ailment which are not on the same scale as the allergies claimed by Applicants’ claimed invention. With respect to Rutala, Rutala fails to teach or even mention “allergies” or “allergens” as a potential target of hypohalous acid.

Fourth, Applicants assert that Camper and Rutala do not disclose that the allergic response is selected from the group consisting of skin rash, hay fever, sneezing, runny nose, red eyes and mixtures thereof as recited in claim 25. While Camper discloses allergies generally in the specification, Camper fails to disclose which allergic responses its invention is directed to as countless number of allergic responses can be found in the literature. Furthermore, Camper fails to disclose any examples involving allergies, let alone allergic responses in the “Examples section” of the specification. The Examples in Camper relate to severe ailments and diseases such as HIV, hemorrhoids or respiratory ailment which are not on the same scale as the allergic responses claimed by Applicants’ claimed invention. Moreover, Rutala fails to teach or even mention “allergies” or “allergic responses” as a potential target of hypohalous acid.

Therefore, a *prima facie* case obviousness rejection cannot be maintained.

(2) There is no suggestion or motivation to modify teachings of the reference

As discussed and supported above, Camper and Rutala both fail to suggest, implicitly or explicitly, that their method comprises the subcutaneous injection of allergens that had been treated with a composition. As discussed and supported above, Camper and Rutala both fail to suggest, implicitly or explicitly, testing an already inactivated allergen solution by using a subcutaneous injection of the already inactivated allergen solution in animal and evaluating that response. As discussed and supported above, Camper and Rutala both fail to suggest, implicitly or explicitly, that an allergen is selected from the group consisting of pollen, mold, pet dander, dust mite, cockroach and mixtures thereof. Additionally, the primary reference, Camper and Rutala both fail to suggest, implicitly or explicitly, that the allergic response is selected from the group consisting of skin rash, hay fever, sneezing, runny nose, red eyes and mixtures thereof. In

fact, the primary reference, Camper, teaches away from Applicants' claimed invention by disclosing severe ailments and diseases, which are not associated with allergies. See the Examples section of the published application. Moreover, Camper and Rutala both fail to suggest, implicitly or explicitly, a subcutaneous injection comprising using a sample from treatment of the allergen with the composition for skin prick testing on animals who had a history of positive skin prick.

(3) Camper and Rutala do not provide a reasonable expectation of success

Camper and Rutala both fail to provide a reasonable expectation of success in performing Applicant's invention. As discussed and supported above, Camper and Rutala both fail to suggest, implicitly or explicitly, that their method comprises the subcutaneous injection of allergens that had been treated with a composition. Moreover, Camper and Rutala both fail to suggest, implicitly or explicitly, testing an already inactivated allergen solution by using a subcutaneous injection of the already inactivated allergen solution in animal and evaluating that response. Additionally, there is nothing in Camper and Rutala that suggests, implicitly or explicitly, an allergen is selected from the group consisting of pollen, mold, pet dander, dust mite, cockroach and mixtures thereof. Furthermore, Camper and Rutala also fail to suggest, implicitly or explicitly, that the allergic response is selected from the group consisting of skin rash, hay fever, sneezing, runny nose, red eyes and mixtures thereof. Additionally, Camper and Rutala also fail to suggest, implicitly or explicitly, a subcutaneous injection comprising using a sample from treatment of the allergen with the composition for skin prick testing on animals who had a history of positive skin prick. Therefore, Camper and Rutala offer no guidance to one of ordinary skill in the art regarding an allergen is selected from the group consisting of pollen, mold, pet dander, dust mite, cockroach and mixtures thereof, an allergic response is selected from the group consisting of skin rash, hay fever, sneezing, runny nose, red eyes and mixtures thereof and a subcutaneous injection comprising using a sample from treatment of the allergen with the composition for skin prick testing on animals who had a history of positive skin prick. Therefore, a *prima facie* case of obviousness rejection cannot be maintained.

In re Appln. of SHAHEEN et al.  
Serial No.: 10/806,522

Because Camper and Rutala fail to teach all of the claimed elements, do not contain a suggestion or motivation to modify reference teachings and do not provide a reasonable expectation of success, a *prima facie* case of obviousness cannot be set forth. Thus, Applicants respectfully request withdrawal of the rejection.

### **CONCLUSION**

In view of the foregoing amendments and remarks, Applicants submit that the application is in condition for allowance. If, however, some issue remains which the Examiner feels may be addressed by Examiner's amendment, the Examiner is cordially invited to call the undersigned for authorization.

In view of the foregoing amendments and remarks, Applicants request entry of the amendments and reconsideration of the rejections. If some issue remains which the Examiner feels may be addressed by Examiner's amendment, the Examiner is cordially invited to call the undersigned for authorization.

Please charge any additional fees, including fees for additional extensions of time, or credit overpayment to Deposit Account No. 03 2270.

Respectfully submitted,

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